K133284

NOV 2 2 2013

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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Date Prepared: November 22, 2013

Device Name

Proprietary name:	Elecsys CK-MB CalCheck 5
Common name:	CK-MB CalCheck 5
Classification:	21 CFR 862.1660, Single (specified) analyte controls (assayed and unassayed)
Product Code:	JJX

Device Description

The Elecsys CK-MB CalCheck 5 is a lyophilized product consisting of human creatine kinase MB isoenzyme (CK-MB) in a human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A. However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.

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510(k) Summary, Continued

Intended use	For use in calibration verification and for use in the verification of the assay range established by the Elecsys CK-MB reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.
Predicate device	The Elecsys CK-MB CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys CK-MB CalCheck 5 (K093582).
Performance Characteristics	The Elecsys CK-MB CalCheck 5 was evaluated for value assignment and stability. See the following sections for details.
Traceability	The Elecsys CK-MB CalCheck 5 was standardized against the Elecsys CK-MB STAT assay, which is traceable to the Abbott IMx assay and linearized using human recombinant CK-MB from Seradyn.

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Substantial Equivalence Comparison

The following table compares the CK-MB CalCheck 5 with the predicate device, Elecsys CK-MB CalCheck 5 (K093582).

Characteristic	Elecsys CK-MB CalCheck 5 (Candidate)	Elecsys CK-MB CalCheck 5 (K093582)
Intended Use	The Elecsys CK-MB CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys CK-MB reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	Same
Analyte	Human CK-MB	Same
Matrix	Human serum matrix	Same
Levels	Five	Same
Format	Lyophilized	Same
Handling	Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion to ensure homogeneity.	Same
Stability	Unopened: Store at 2-8°C until expiration date Opened: 20-25°C: 4 hours	Same

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Value Assignment

Value assignment testing was conducted and passed pre-defined acceptance criteria. For each Elecsys CK-MB CalCheck 5 lot manufactured, the CalChecks are run in duplicate on at least three Elecsys 2010 analyzers. The assigned value of each CalCheck is defined as the median value obtained over at least 6 determinations (duplicate runs on at least 3 analyzers) of the respective CalCheck. The assigned range is calculated as ±27% of assigned value for level 2 and as ±30% of the assigned value for levels 3 through 5. The label states that each laboratory should establish appropriate acceptance criteria when using this product for its intended use.

The same value assignment procedure is performed on the MODULAR ANALYTICES E170. The assigned values obtained are compared to those obtained on the Elecsys 2010. The median value obtained on the additional analyzer must be within 10% of the master platform assigned value. After this acceptance criterion is met, the assigned values from the master platform are deemed valid for the MODULAR ANALYTICS E170, Elecsys 2010, **cobas e** 411, **cobas e** 601, and **cobas e** 602 immunoassay analyzers.

Stability

Real-time and open-vial stability tests were conducted to establish the shelf-life and open-vial claims.

Open-Vial Stability After Reconstitution:

Testing was performed and the data support the package insert claim that reconstituted Elecsys CK-MB CalCheck 5 is stable up to 4 hours at 20-25°C.

Shelf-Life Stability:

Real-time testing done at 2-8°C supports a claim of 36 months.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

ROCHE DIAGNOSTICS
KELLI TURNER
REGULATORY AFFAIRS PRINCIPAL
9115 HAGUE ROAD, P.O. BOX 50416
INDIANAPOLIS IN 46250-0416

Re: K133284
Trade/Device Name: Elecsys CK-MB CalCheck 5
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJX
Dated: October 24, 2013
Received: October 25, 2013

Dear Ms. Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
k133284

Device Name
Elecsys CK-MB CalCheck 5

Indications for Use *(Describe)*
The Elecsys CK-MB CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys CK-MB reagent on the indicated Elecsys and cobas e immunoassay analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ruth A. Chesler -S